

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
USA

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BY:

27 April 2004

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NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

On behalf of Ferrosan A/S, Sydmarken 5, DK-2860 Soeborg, Denmark, the undersigned files this notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6). The certification required by 21 C.F.R. § 101.93(a)(3) is attached.

Brand Name

Imedeen time perfection

Dietary Ingredients:

Bio Marine Complex (Fish protein, polysaccharides)

LycoPhence GS (Oliogomeric Procyanidins (OPC) (from Grape seed extract), Lycopene (from Tomato Extract)

Vitamin C

Statements of Nutritional Support:

- Improves quality, structure and appearance of photo aged skin by:
- · Nourishes skin from within
- Improves the moisture content of the skin
- Improves the structure and density of the dermal layer of the skin
- Decreases the visibility of fine lines and wrinkles
- Decreases visibility of hyper pigmentation and age spots
- · Reduces pore size
- Decreases laxity, improving firmness of the skip75 0162

Ferrosan A/S Sydmarken 5 2860 Soeborg Denmark

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www.ferrosan.com

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- Decreases a dull, matte appearance, giving the skin glow
- Decreases skin roughness/improves smoothness
- Decreases under-eye dark circles and bags
- Reduces the visibility of dilated capillaries and liver spots
- Decreases blotchiness
- Improves overall appearance of the facial skin
- Improves the quality and structure of skin
- Improves the smoothness and dryness of the body skin
- Defends skin against structural elements from age-related changes, thereby helping fight against future signs of aging by:
- Rapidly beings to neutralize the skin degrading proces
- Instantaneously deactivating various types of free radicalsⁱ
- Helping to defend collagen and elastin fibres and glucosaminoglycans against free radical induced enzymatic breakdown

Yours sincerely, Ferrosan A/S

Malene Metz Mørch Development/Director

> Ferrosan A/S Sydmarken 5 2860 Soeborg Denmark

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Attachment - Certification

21 C.F.R. § 101.93(a)(3) Certification

I certify that the information contained in the preceding section 403(r)(6) notice for Imedeen time perfection is complete and accurate and that Ferrosan A/S has substantiation that the statements are truthful and not misleading.

Malene Metz Mørch Development Director

27 April 2004

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